



Attorney Docket No: 2002971-0039

#22/Brief
6/28/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Johansen, *et al.* Examiner: M. Brown

Serial No.: 09/086,508 Art Unit: 3764

Filing Date: May 28, 2000

Title: BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

APPELLANT'S BRIEF UNDER 37 CFR § 1.192

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Real Party in Interest

By virtue of an assignment recorded at reel 9333, frame 0905, the present application is assigned to Innovative Devices, Inc., which is a wholly owned subsidiary of the Johnson & Johnson Company.

Related Appeals and Interferences

An appeal is currently pending in U.S. Application No. 09/332,965, which is a divisional of U.S. Application No. 08/814,149, now issued as U.S. Patent No. 5,911,721. The present application is a continuation-in-part of the latter patent.

Status of Claims

Claims 1-6, 10-21, and 25-28 are currently pending in the application. Claims 25-28 have been allowed and are not at issue in this appeal. Claims 1-6 and 10-21 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,012,984 to Matuschek.

Status of Amendments

There are no unentered amendments. The claims involved in this appeal are set forth in the Appendix.

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Summary of Invention

The present invention comprises a bone anchor, usable for attaching soft tissue to bone. Each of the claims at issue in this appeal recites a rivet, an expandable sleeve, and a washer capable of both longitudinal and limited angular rotation relative to the rivet. The anchor is set by inserting the rivet into the expansion element, thereby expanding it into contact with a bone tunnel to hold it in place.

In claims 1-6, the recited washer “floats.” This term is defined in the specification at page 9, lines 26-28 to mean that the washer is capable of both longitudinal and limited angular rotation. In claims 10-21, the language “capable of both longitudinal and limited angular rotation” is used explicitly. This property of the washer allows it to conform to the relatively uneven surface of the underlying bone, securing tissue to bone without exerting undue pressure on the tissue.

Allowed claims 25-28 (not at issue in this appeal) relate to methods of placing the anchor in a bone tunnel.

Issues

The issue in this appeal is whether claims 1-6 and 10-21 are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,012,984 to Matuschek.

Grouping of Claims

The claims do not stand or fall together. As set forth in the following section, the claims contain different limitations distinguishing them from the cited art, and thus should be separately considered.

Argument

Independent claims 1, 5, and 10 are not anticipated by Matuschek, because that reference does not include all of the limitations of any of the claims. Since none of the independent claims are anticipated, dependent claims 2-4, 6, and 11-21 also cannot be anticipated.

Procedural history

The appealed claims were rejected in the first Office Action mailed on June 22, 1999 as anticipated by Matuschek. Applicants argued in the Office Action Response filed on July 29, 1999, that the present invention was distinct from Matuschek because the latter did not include a floating washer. In a final Office Action, the Examiner responded that the “floating” nature of the washer was a functional limitation entitled to no weight in determining patentability.

Applicants expanded on their original arguments in an additional Office Action Response filed on March 24, 2000. The Examiner responded with an Advisory Action stating that “claims 1-6 and 10-21 remain finally rejected,” but without stating reasons for rejection or whether Applicants additional arguments were considered. Applicants filed a Continuing Prosecution Application in the hopes of obtaining more detailed reasons for the rejection of the claims, but their arguments of March 24, 2000 were still not addressed in the Office Action mailed on May 18, 2000, which is the decision appealed herein.

The law of “functional” claiming

Since many of the Examiner’s rejections are based on the fact that the claims contain “functional” limitations, the law regarding such limitations is briefly reviewed before addressing the individual claims.

Applicants are entitled to use functional language in claims. *See In re Swinehart*, 58 C.C.P.A. 1027, 169 U.S.P.Q. 226 (1971). Further, functional limitations in claims must be considered when determining claim scope. *See, e.g., ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 U.S.P.Q.2d 1321 (Fed. Cir. 1998). It is true that “[a]pparatus claims cover what a device *is*, not what a device *does*.” MPEP 2114 (quoting *Hewlett-Packard Co. v. Bausch & Lomb, Inc.* 909 F.2d 1464, 1469, 15 U.S.P.Q.2d 1525, 1528 (1990)). This requirement means that functional limitations must actually impose limitations on the structure of a device in order to confer patentability. If an identical device is disclosed in the prior art, a new method of using it will not confer patentability of the device. However, if the “functional” language actually limits the types of apparatus that fall within the claims, it must be considered. Stated another way, if the prior art device is actually not *capable* of carrying out the claimed function (as opposed to

not *disclosed* to carry out the function), then the limitation distinguishes over the prior art device and the claim is not anticipated.

Claims 1-4

As discussed above, claims 1-4 recite “a washer which floats at an end of the expandable sleeve which first receives the rivet.” The specification defines “float” at page 9, lines 26-28, as “capable of at least longitudinal motion and limited angular motion.”

Matuschek discloses a blind rivet assembly designed to require fewer steps to deploy in an industrial process. The assembly includes a pressure washer (13) on the rivet head. The pressure washer must closely abut the shaft of the intermediate portion (8), so that it can be used to crimp the rivet skirt (21) to form annular rib (29), as most clearly shown in Figure 4. Thus, it does not “float” within the meaning of claims 1-4, and is not anticipated thereby.

The floating nature of the washer is an important element of the claimed invention, because the limited angular rotation of the washer is what allows it to conform to the bone surface upon deployment (as further recited in claims 1-4). The washer (13) of Matuschek cannot conform to the surface of the element being secured, because it does not extend beyond the head (2) of the rivet, as most clearly shown in Figures 1 and 2.

The rivet of Matuschek is thus not only not *disclosed* to carry out the claimed functions, but is not *capable* of carrying out the claimed functions. Since the “functional” limitations place actual limits on the structures encompassed by the instant claims, and since the prior art does not meet those limitations, the rejection of claims 1-4 under 35 U.S.C. § 102(b) should be reversed.

Claims 5 and 6

Claims 5 and 6 recite “a floating washer that is disposed about the expandable sleeve and that floats relative thereto.” The arguments presented above with respect to claims 1-4 concerning the “floating” nature of the washer are equally applicable to claims 5 and 6 and are incorporated by reference herein.

In addition, claims 5 and 6 recite that motion of the body of the rivet into the expandable sleeve “secures the floating washer relative to the bone.” In contrast, the washer (13) of Matuschek is not secured by expansion of the sleeve. In fact, it probably does not even remain in

contact with the rivet once the sleeve has been expanded and the rivet set. The rivet of Matuschek is disclosed to be “blind,” indicating that once fastened, the head of the rivet is flush with the work. *See, e.g.*, column 2, lines 58-60, describing the importance of assuring that the break is flush. No structure is disclosed for securing the rivet. Since the washer sits above the rivet head, Applicants infer that it is not intended to remain in contact with the work once the rivet is fastened, and therefore is not “secured” within the meaning of claims 5 and 6.

Since neither the limitation that the washer float nor the limitation that the washer be secured is met by the prior art, the rejection of claims 5 and 6 under 35 U.S.C. § 102(b) should be reversed.

Claims 10-21

Claims 10-21 recite “a washer ... which is capable of both longitudinal motion and of limited angular rotation relative to the head of the rivet.” The arguments presented above with respect to claims 1-4 concerning the “floating” nature of the washer are equally applicable to claims 10-21 and are incorporated by reference herein.

Claims 10-21 further recite that the head of the rivet is “adapted to sandwich the washer between the tissue and the head of the rivet.” This limitation also excludes the rivet of Matuschek. In order to sandwich the washer between the tissue and the head of the rivet, the head of the rivet must be disposed above the washer, allowing it to bear down on the washer and tissue (or the work of Matuschek). As clearly shown in the figures of Matuschek, the washer (13) is *above* the head (2) of the rivet, and is not secured thereby (as discussed above). Since the head of the rivet *cannot* sandwich the washer between the tissue and the head of the rivet, this limitation of the claims is not met by Matuschek.

Since neither the limitation that the washer be capable of at least limited angular rotation nor that the head of the rivet be able to sandwich the washer between the head of the rivet and the tissue is met, the rejection of claims 10-21 under 35 U.S.C. § 102(b) should be reversed.

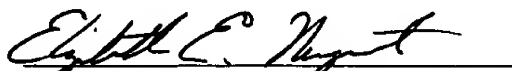
Conclusion

All of the appealed claims contain limitations not met by Matuschek. These limitations are not simply “use” limitations, but impose actual structural limits on the claimed device. Since

the functionally recited claim elements *cannot* be met by the cited art, the claims are not anticipated under 35 U.S.C. § 102(b) and the rejections should be reversed.

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Respectfully submitted,



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on 6/13/01
Susan M. Dinsmore

APPENDIX

1. A bone anchor comprising:

a rivet which includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body;

an expandable sleeve having an inner bore adapted to receive the elongate body of the rivet; and

a washer which floats at an end of the expandable sleeve which first receives the rivet;

wherein, as the rivet is received in the expandable sleeve, the sleeve expands in an interference fit with surrounding bone and the head of the rivet forces the washer into contact with tissue adjacent to the bone, the washer being forced into contact with the tissue at an angle that conforms to an angle of a surface of the bone.

2. A bone anchor according to claim 1, wherein an external surface of the expandable sleeve includes one or more protrusions.

3. A bone anchor according to claim 1, wherein the rivet includes a centerbore which is capable of receiving any of a guide wire, guide pin and K-wire.

4. A bone anchor according to claim 1, further comprising:

a housing which is frangibly coupled to the expandable sleeve via breakable flanges, the housing being adapted to store the rivet prior to insertion of the rivet into the expandable sleeve, and being adapted to affix the bone anchor to a delivery device;

wherein, during deployment of the bone anchor, the head of the rivet breaks the flanges of the housing, thereby freeing the housing from the bone anchor.

5. A bone anchor for attaching tissue to bone, the bone anchor comprising:

a rivet having an elongate body and a head disposed on a proximal end thereof;

an expandable sleeve for insertion into an opening in a bone, the expandable sleeve having an inner bore adapted to receive at least a portion of the elongate body of the rivet; and

a floating washer that is disposed about the expandable sleeve and that floats relative thereto;

wherein motion of the portion of the elongate body of the rivet within the inner bore of the expandable sleeve from a proximal end to a distal end thereof causes (i) the expandable sleeve to expand into an interference fit with the bone, and (ii) secures the floating washer relative to the bone.

6. A bone anchor according to claim 5, wherein the floating washer is secured to the bone at an angle that substantially corresponds to a surface of the bone.

10. A bone anchor for attaching tissue to a bone, the bone anchor comprising:

a rivet which includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body;

an expandable sleeve which is adapted to move between an unexpanded state and an expanded state, the expandable sleeve having an inner bore which is adapted to receive the elongate body of the rivet distal-end-first so as to cause the expandable sleeve to go from the unexpanded state to the expanded state; and

a washer which surrounds the expandable sleeve and which is capable of both longitudinal motion and of limited angular rotation relative to the head of the rivet, wherein the head of the rivet is adapted to sandwich the washer between the tissue and the head of the rivet when the bone anchor is deployed in the bone so as to hold the tissue substantially in place relative to the bone.

11. A bone anchor according to claim 10, wherein the elongate body has a first diameter and, when the expandable sleeve is in an unexpanded state, the inner bore of the expandable sleeve has a second diameter which is less than the first diameter; and

wherein the distal end of the elongate body comprises a tapered tip, the tapered tip having a diameter which gradually decreases to less than the second diameter of the inner bore.

12. A bone anchor according to claim 10, wherein an external surface of the expandable sleeve includes one or more protrusions.

13. A bone anchor according to claim 10, wherein the rivet includes a centerbore which is capable of receiving any of a guide wire, guide pin and K-wire.

14. A bone anchor according to claim 10, further comprising
a housing which is removably connected to the expandable sleeve via breakable flanges, the housing being adapted to store the rivet prior to insertion of the rivet into the expandable sleeve;

wherein the head of the rivet is adapted to contact the breakable flanges during deployment of the bone anchor so as to break the breakable flanges, thereby disconnecting the housing from the expandable sleeve and leaving the bone anchor in the bone.

15. A bone anchor according to claim 14, wherein the housing has a substantially cylindrical shape and mates to a deployment device used to deploy the bone anchor in bone.

16. A bone anchor according to claim 10, wherein the head of the rivet has an undersurface for contacting the washer, the rivet having an undersurface that is any of radiused or angled relative to an axis of the elongate body.

17. A bone anchor according to claim 10, wherein the washer has a top surface which interacts with the head of the rivet and which is any of radiused or angled relative to an undersurface of the head of the rivet.

18. A bone anchor according to claim 10, wherein, when the bone anchor is deployed in the bone, the rivet holds the washer at an angle relative to the head of the rivet such that the washer is substantially parallel to a surface of the bone.

19. A bone anchor according to claim 10, wherein at least one of the rivet, the washer, and the sleeve are bioabsorbable.

20. A bone anchor according to claim 10, wherein the rivet includes one or more annular ribs.

21. A bone anchor according to claim 10, wherein the sleeve may include one or more slots which runs at least part way along the sleeve.